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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/381,480	12/10/99	CHEE	M 018547-03053

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EXAMINER	
CHAKRABARTI,A	
ART UNIT	**PAPER NUMBER**
1655	5

DATE MAILED: 07/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/381,480	Chee
Examiner	**Group Art Unit**
Arun Chakrabarti	1655

☒ *Responsive to communication(s) filed on* Dec 10, 1999 .

☐ *This action is* **FINAL.**

☐ *Since this application is in condition for allowance except for formal matters,* **prosecution as to the merits is closed** *in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.*

A shortened statutory period for response to this action is set to expire 3 *month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).*

Disposition of Claims

☒ *Claim(s)* 1-15 *is/are pending in the application.*

Of the above, claim(s) _____ *is/are withdrawn from consideration.*

☐ *Claim(s)* _____ *is/are allowed.*

☒ *Claim(s)* 1-15 *is/are rejected.*

☐ *Claim(s)* _____ *is/are objected to.*

☐ *Claims* _____ *are subject to restriction or election requirement.*

Application Papers

☐ *See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.*

☐ *The drawing(s) filed on* _____ *is/are objected to by the Examiner.*

☐ *The proposed drawing correction, filed on* _____ *is* ☐*approved* ☐*disapproved.*

☐ *The specification is objected to by the Examiner.*

☐ *The oath or declaration is objected to by the Examiner.*

Priority under 35 U.S.C. § 119

☐ *Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).*

☐ *All* ☐ *Some** ☐ *None of the CERTIFIED copies of the priority documents have been*

☐ *received.*

☐ *received in Application No. (Series Code/Serial Number)* _____ .

☐ *received in this national stage application from the International Bureau (PCT Rule 17.2(a)).*

**Certified copies not received:* _____ .

☐ *Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).*

Attachment(s)

☒ *Notice of References Cited, PTO-892*

☐ *Information Disclosure Statement(s), PTO-1449, Paper No(s).* _____

☐ *Interview Summary, PTO-413*

☐ *Notice of Draftsperson's Patent Drawing Review, PTO-948*

☐ *Notice of informal Patent Application, PTO-152*

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite over the recitation of the phrase, "true sequence". It is unclear how this is determined and what is meant by "true".

Claim 8 is vague and indefinite over the recitation of the phrase, "a position of ambiguity". It is not clear what is meant by ambiguity. Is it a deletion mutation, insertion mutation or both or what is the reason of ambiguousness in a target nucleic acid. The term must be defined clearly and distinctly. It is also unclear whether the phrase following "having including" is an essential part of the claimed invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 1, 2, and 5-15 are rejected under 35 U.S.C. 102 (e) as being anticipated by Cronin et al. (U.S. Patent 6,027,880) (February 22, 2000).

Cronin et al. teach a method of analyzing a target nucleic acid (abstract), comprising:

a) providing an array of probes comprising a probe set comprising probes complementary to a reference sequence (Column 5, lines 53-58 and Figure 10 and claim 28, column 164, lines 22-35);

b) hybridizing the target nucleic acid to the array of probes (Column 5, lines 53-58 and Figure 10 and claim 28, column 164, lines 22-35);

c) determining the relative hybridization of the probes to the target nucleic acid (Column 5, lines 53-58 and Figure 10 and claim 28 , column 164, lines 22-35);

d) estimating the sequence of the target nucleic acid from the relative hybridization of the probe (Column 5, lines 53-58 and Figure 10 and claim 28, column 164, lines 22-35););

e) providing a further array of probes comprising a probe set comprising probes complementary to the estimated sequence of the target nucleic acid (Column 5, lines 58-60 and Figure 10 and claim 28, column 164, lines 38-46);

f) hybridizing the target nucleic acid to the further array of probes (Column 5, lines 58-60 and Figure 10 and claim 28, column 164, lines 38-46);

g) determining the relative hybridization of the probes to the target nucleic acid (Column 5, lines 58-60 and Figure 10 and claim 28, column 164, lines 38-46);

h) reestimating the sequence of the target nucleic acid from the relative hybridization of the probes (Column 5, lines 58-67 and Figure 10 and claim 28, column 164, lines 46-62).

Cronin et al. teach a method further comprising repeating steps (e)-(h) as necessary until the reestimated sequence of the target nucleic acid is the true sequence of the target nucleic acid (claim 28, column 164, lines 46-62).

Cronin et al. teach a method wherein the target nucleic acid shows 50-99% sequence identity with the reference sequence (Column 49, lines 30-31 and column 50, lines 1-53).

Cronin et al. teach a method wherein the reference sequence is 10 Kb nucleotides long, the array comprises a probe set comprising overlapping probes that are perfectly complementary to and span the reference sequence, and the further array comprises probes that are perfectly complementary to and span the estimated sequence (Table 3, column 63 and 64, Mutation Number 3849).

Cronin et al. teach a method wherein the reference sequence includes at least 90% of the human genome (Column 42, lines 15-25).

Cronin et al. teach a method wherein the array of probes comprises:

(1) a first probe set comprising a plurality of probes, each probe comprising a segment of at least six nucleotides exactly complementary to a subsequence of the reference sequence, the

segment including at least one interrogation position complementary to a corresponding nucleotide in the reference sequence (Figure 3),

(2) second, third and fourth probe sets, each comprising a corresponding probe for each pribe in the first probe set, the probes in the second, third and fourth probe sets being identical to a sequence comprising the corresponding probe from the first probe set or a subsequence of at least six nucleotides thereof that includes the at least one interrogation position, except that the at least one interrogation position is occupied by a different nucleotide in each of the four corresponding probes from the four probe sets (Figures 3, 7, 8 and 9 and Claim 28).

Cronin et al. teach a method wherein the sequence of the target nucleic acid is estimated by :

a) comparing the relative specific binding of four corresponding probes from the first, second, third and fourth probe sets (Column 164, claim 28, lines 51-53);

b) assigning a nucleotide in the sequence of the target nucleic acid as the complement of the interrogation position of the probe having the greatest specific binding (Column 164, claim 28, lines 54-56);

c) repeating (a) and (b) until each nucleotide of interest in the sequence of the target nucleic acid has been estimated (Column 164, claim 28, lines 57-61);

Cronin et al. teach a method wherein the sequence of the target nucleic acid differs from the reference by at least two positions within a probe length (Column 35, lines 1-6).

Cronin et al. teach a method of analyzing a target nucleic acid by designing an array of probes to be complementary to an estimated sequence of the target nucleic acid (Column 31, lines 42 to column 33, line 67).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103 (a) over Cronin et al. (U.S. Patent 6,027,880) (February 22, 2000) in view of Horwitz et al. (Journal of Virology, (1992), Vol. 66 (4), pages 2170-2179).

Cronin et al teach method of claims 1, 2, and 5-15 as described above.

Cronin et al do not teach method wherein the target nucleic acid sequence is a species variant of the reference sequence and wherein the reference sequence is from a human and the target nucleic acid is from a primate.

Horwitz et al teach method wherein the target nucleic acid sequence is a species variant of the reference sequence and wherein the reference sequence is from a human and the target nucleic acid is from a primate (Abstract and Figures 1 and 3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to include the comparative primate versus human gene sequence study of Horwitz et al. in the method of Cronin et al., since Horwitz et al. states "Because of the recent identification of several classes of human endogenous retroviruses and our interest in obtaining a better understanding of the evolution of human immunodeficiency virus (HIV), experiments were performed to detect the presence of HIV-1 related sequences in normal human DNA (Page 2170, column 2, second paragraph, lines 1-6)." An ordinary practitioner would have been motivated to combine the comparative primate versus human gene sequence study of Horwitz et al. in the method of Cronin et al. in order to achieve the express advantages noted by Horwitz et al. of obtaining a better understanding of the evolution of human immunodeficiency virus (HIV).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,

Patent Examiner,

June 30, 2000

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,

Patent Examiner,

June 30, 2000

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

7/5/00